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A Retrospective Study of Six Sigma Methodology to Reduce Inoperability among Lung Cancer Patients

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Abstract

In this study, the authors aim to examine the root causes of the delays in reaching a definitive diagnosis of lung cancer in time and investigate to reduce it by Six Sigma Methodology. The SIPOC table, Fishbone diagram and FMEA table are generated. Thirteen types of causes are identified. They cause patients with lung disease to enter the Stage IIIB and Stage IV. It is concluded that absence of patient's check-up habit and patient's anxiety and worry that cause late admission to doctor are the crucial causes of delays that may lead to inoperability.

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Keywords: Lung cancer, Inoperability, Delays, Root causes, Six Sigma

1. Introduction

Lung cancer is a major global health problem and a leading cause of death in both men and women. After prostate cancer, it is the second most common fatal type of cancer in men and the fourth most common fatal type of cancer after breast, colorectal and uterus cancers in women (Ferlay et al., 2013).

In the last few decades, there has been a large increase in the number of cases of lung cancer in developing countries. The estimated numbers of lung cancer cases worldwide has increased by 51% since 1985 (Charles et al.,

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2011). Globally, there are an estimated 1.4 million deaths each year which represents 18.4% of cancer deaths (Ferlay et al., 2013).

The American Cancer Society's estimates for lung cancer in the United States for 2015 are about 221,200 new cases of lung cancer (115,610 in men and 105,590 in women); and 158,040 deaths from lung cancer (86,380 in men and 71,660 among women) (American Cancer Society, 2014).

Statistics that compare aspects of quality of care for people with lung cancer are limited in Turkey. While lung cancer is the most common fatal type of cancer in Turkish men with an incidence of 60.57±0.61/100.000 people, it is the sixth most common cancer in Turkish women after breast, thyroid, colorectal, uterus and stomach cancers (Turkish Ministry of Health, 2015). It is observed in Turkey that 59.4% of lung cancer cases have made distant metastasis (Turkish Ministry of Health, 2015).

Diagnosis of stage for any type of cancer is essential for treatment recommendations. Once an accurate objective staging process has been established; then, treatment recommendations can be made. Surgery has been shown to be the most effective form of treatment for lung cancer. However, IIIB and IV are the stages of inoperability for lung cancer patients. In the United States, the observed survival rates for Stage IIIB and Stage IV are 5% and 1%, respectively (The National Cancer Institute, 2015). Since these cancers have spread to nearby and/or distant sites, they are very hard to cure and surgery is not an option for treatment. Thus, timely diagnosis is crucial for curing the patients at risk. Reducing the causes of delays is of utmost importance for saving patients' lives.

Cancer survival is crucial but delayed diagnosis can also have a negative effect on quality of life, with the use of more toxic treatments when cancer is diagnosed at Stage IIIB or Stage IV, and an increase in psychological distress (Risberg et al., 1995).

The majority of lung cancers (>80%) are diagnosed and treated at an advanced stage, i.e. stage IIIB and IV, by when they are beyond the scope of curative resection (Chandra et al., 2009; Mountain, 1997). This may, in part, be due to a long delay between the onset of symptoms and establishment of a diagnosis and finally, initiation of treatment.

National Patient Safety Agency (2010) stated that delays might result from three sources: patient, healthcare practitioner or provider and system. They focused on patient delay in the diagnostic journey. They defined patient delay as the length of time an individual will be aware of symptoms before seeking healthcare practitioner advice, and highlighted the risk factors as symptom recognition and interpretation, psychological factors and socio-demographic/ethnicity factors.

Dependent on several modifiable and non-modifiable causes, delay is variable and ranges from three to six months in Western countries (Billing and Wells, 1996). The causes of delay include lack of patient awareness of the disease, lack of accessibility to health care, and aggressiveness of the diagnostic approach (Chandra et al., 2009). In addition, these causes lead to a situation in which curable disease becomes incurable. Since many of these causes are modifiable, it was crucial to quantify the delay from symptom onset to treatment, as this had definite implications on patient survival (Chandra et al., 2009).

Singh et al. (2010) stated that understanding delays in cancer diagnosis requires detailed information about timely recognition and follow-up of signs and symptoms. They reviewed 587 new patients with lung cancer of two tertiary institutions and reported that 38% of cases had missed the opportunities to establish a diagnosis of lung cancer. They concluded that preventable delays in lung cancer diagnosis arose mostly from failure to recognize documented abnormal imaging results and failure to complete key diagnostic procedures in a timely manner. In addition, they stated that potential solutions include electronic health record-based strategies to improve recognition of abnormal imaging and track patients with suspected lung cancers (Singh et al., 2010).

Both O'Rourke and Edwards (2000) and Mohammed et al. (2011) described tumor progression and inoperability following delays in starting treatment. O'Rourke and Edwards (2000) concluded that limited access to specialists was the reason for the poor performance in treating lung cancer in the UK. They demonstrated that the outcome was prejudiced by waiting times that allowed tumor progression. On the other hand, Mohammed et al. (2011) concluded that diagnosis, staging, and treatment initiation should be expedited.

Gonzalez et al. (2003) studied the clinical and demographic factors associated with delays in the diagnosis of lung cancer. They concluded that the attitudes of primary care physicians and their relations with specialized care providers were crucial for reducing delays.

Myrdal et al. (2004) studied two types of delays: symptom to treatment delay and hospital delay. Their results indicated that longer delay before treatment of lung cancer patients was not associated with a poorer prognosis, indicating that patients with more advanced disease received treatment more promptly because of the severity of their signs and symptoms.

A systematic review from Olsson et al. (2009) found that there was no clear evidence that a timely diagnostic pathway could result in improved survival.

To date, no quality improvement method has been applied to decrease cancer related mortality rate. Being important dimensions of health care quality; early detection, timely diagnosis and treatment of lung cancer will reduce mortality rate and improve quality of life. To achieve these, authors used a continuous quality improvement method named Six Sigma. In this study, statistical tools of Six Sigma were used in order to calculate and report the causes of delay in terms of sigma level.

2. Methods

A total of 277 consecutive patients with stage IIIB and IV lung cancer between February 2011 and March 2014 in a chest diseases clinic at a private hospital were included in the study. The hospital records of 46 (16.6%) patients were not available for this retrospective study, and these patients have therefore been excluded from the analysis. As a result, the study was completed with 231 patients.

The mean age of the patients was 56.1±11.9 years. 72(31.1 %) of the patients were female and 149 (68.9 %) were male. All clinical information and doctor visits were retrospectively reviewed from patients file. Structured telephone or face-to-face interviews with patients and/or their relatives were conducted using a standardized data collection form. All chest radiographs were reinterpreted by two radiologists. One pathologist re-examined all pathologic results.

The authors made use of descriptive statistics and Six Sigma's tools to measure the causes of delays that lead to inoperability. Normal distribution underlies Six Sigma's statistical assumptions. An empirically-based 1.5 sigma shift is introduced into the calculation. A higher sigma level indicates a lower number of causes and a more efficient process.

The authors calculated the current defective parts per million opportunities (DPMO) and sigma level for each type of cause. For the calculations, the authors made use of two distinct datasets, i.e. total number of lung cancer patients in the chest diseases unit (TP) and total number of lung cancer patients who experienced that type of cause (TC). Then, the DPMO can be calculated from Equation 1 as follows:

$$DPMO = TC \times 1{,}000{,}000/TP \tag{1}$$

Sigma level for each type of cause is then calculated from DPMO by taking ratios as a Six Sigma level produces 3.4 DPMOs.

3. Analysis

3.1. Application of Six Sigma's tools

When the chest diseases unit realized that they had been suffering from high rates of lung cancer patients entering the Stage IIIB and Stage IV, they decided to focus attention on prevention and treatment of the causes for delay in the process. Experiencing high rates had resulted in the loss of patients. This was the rationale that the authors decided to implement a quality management system in the unit.

They found that best way to reduce these causes was to initiate Six Sigma statistics and tools. First, they generated a SIPOC (Supplier, Input, Process, Output and Customer) Table (Table 1) for the overall process. Next, they calculated the frequency of each type cause by means of descriptive statistical analysis (Table 2). By interviewing the patients and/or their relatives; the authors traced, recorded the root causes of delay, classified the causes according to type and counted the number of patients that experienced each type of cause (Table 2).

Table 1. SIPOC Table

Supplier	Input	Process	Output	Customer
Doctors (Primary doctor and pathologist) Radiologist Technician	Direct X-ray Chest Tomography Needle Biopsy Bronchoscopy Mediastinoscopy Thoracic Magnetic Resonance Imaging (MRI) Positron Emission Tomography (PET)	Diagnosis of Lung Disease	Incurable Lung Cancer Delayed Lung Cancer	Patient

The authors defined the performance objective of the process as minimized number of inoperable lung cancer patients, i.e. minimum number of delayed causes. To achieve the performance objective, the authors determined the Critical-to-Quality (CTQ) factors by brainstorming. The CTQ factors were those factors that might have a negative influence on the objective. The authors generated a Fishbone diagram depicting the effects of patient, technician, doctor and technology on inoperability. Then, sigma levels of complications were calculated from DPMOs (Table 3). In addition, sources and CTQs were demonstrated per complication type (Table 3).

Table 2. Number of Patients and Frequencies per Root Cause

Type	Root Causes of Delay	Number of Patients	Frequency (%)
I	Absence of patient's check-up habit	51	22.0779
II	Late admission of patient to doctor due to anxiety and worry	48	20.7792
III	Patient's self-prescription	20	8.6580
IV	Patient's decision to use alternative medicine after knowing the tumour and not accepting surgery	12	5.1948
V	Delay in diagnosis due to doctor's direct prescription of medication and patient's avoidance of regular check-up	16	6.9264
VI	Doctor's irregular follow-up of patient's lung nodules that he detected in patient's X-ray films	22	9.5238
VII	Incorrect examination of pathological specimen	6	2.5974
VIII	Misinterpretation of radiologic imaging signs	17	7.3593
IX	Failure to take chest good quality radiograph	8	3.4632
X	Insufficient imaging due to non-periodic maintenance of tomography equipment	14	6.0606
XI	Reaching incomplete or incorrect diagnosis due to taking non-contrast tomography	10	4.3290
XII	Failure to take chest radiograph in correct locus of patient	3	1.2987
XIII	Failure to set an average effective dose of a chest radiograph	4	1.7316

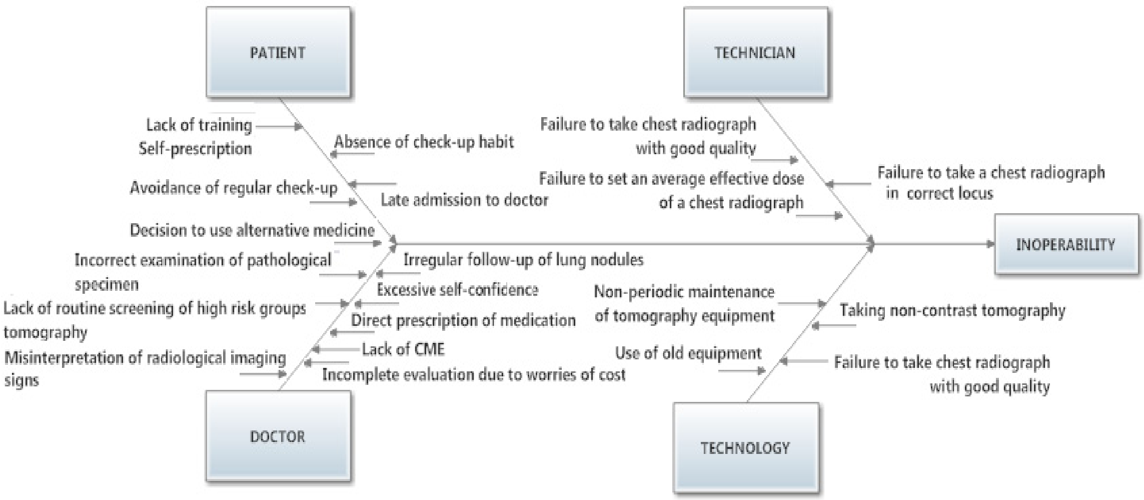

Fig. 1. Fishbone Diagram

Table 3. Sources, CTQ Types, DPMOs and Sigma Levels per Complication Type

Type	Source	CTQ Type	DPMO	Sigma Level
I	Patient	Vital few	220,779	2.2696
II	Patient	Vital few	207,792	2.3141
III	Patient	Trivial many	86,580	2.8621
IV	Patient	Vital few	51,948	3.1263
V	Patient, Doctor	Trivial many	69,264	2.9813
VI	Doctor	Trivial many	95,238	2.8092
VII	Doctor	Trivial many	25,974	3.4436
VIII	Doctor	Vital few	73,593	2.9495
IX	Technician, Technology	Trivial many	34,632	3.3167
X	Technology	Trivial many	60,606	3.0497
XI	Technology	Trivial many	43,290	3.2137
XII	Technician	Trivial many	12,987	3.7266
XIII	Technician	Trivial many	17,316	3.6126

The highest sigma level was obtained for the failure to take chest radiograph in correct position of patient by the radiologist. The lowest sigma level was found to belong to the absence of patient's check-up habit. Having sigma levels lower than 4.00; all types of causes needed to be significantly reduced. The process sigma level, calculated from the arithmetic average of sigma levels of thirteen causes, was found to be 3.0519.

3.2. Failure Mode and Effect Analysis (FMEA)

Risk assessment of the process was achieved by the Failure Mode and Effect Analysis (FMEA). Utilization of the FMEA involved break down the process into individual steps: potential failure modes (i.e. causes of delay), severity score, probability (or occurrence) score, hazard score, criticality and detectability so that the authors could look at key drivers in the whole process based on the past experience.

Occurrence trends and consequences of causes of delay over a 3-year period had been monitored and recorded. The authors prioritized the causes according to how serious their consequences were (i.e. severity score); how frequently they occurred (i.e. probability score) and how easily they could be detected. Hazard analysis was employed in order to identify the possible effects of causes. The authors determined the severity of each type of cause of delay and assigned scores for them. The severity of each cause was scored from 1 to 4 (Table 4).

Table 4. Severity Scores

Severity Score	4	3	2	1
Severity of Cause	Serious harm	Medium harm	Low harm	No harm
Number of Patients	138	55	38	0

For each type of the cause, the hazard score was calculated by multiplying the severity score with the probability score. Then, an FMEA table was drawn (Table 5). Next, the authors compared the hazard scores of the causes.

Among the causes of delay, the absence of patient's check-up habit yielded the highest hazard score. Likewise, patient's anxiety and worry causing his late admission to doctor also yielded a very high hazard score. Being the two more hazardous and more frequent causes that the patients had experienced, these causes also yielded the lowest levels of sigma.

Table 5. FMEA Table

	Hazard Analysis			Decision Tree Analysis	
Type	Severity Score	Probability Score	Hazard Score	Critical?	Detectable?
I	4	0.220779	0.883116	Yes	Yes
II	4	0.207792	0.831168	Yes	Yes
III	3	0.086580	0.259740	Yes	Yes
IV	4	0.051948	0.207792	Yes	Yes
V	2	0.069264	0.138528	No	Yes
VI	3	0.095238	0.285714	Yes	Yes
VII	4	0.025974	0.103896	Yes	Yes
VIII	4	0.073593	0.294372	Yes	Yes
IX	2	0.034632	0.069264	No	Yes
X	2	0.060606	0.121212	No	Yes
XI	3	0.043290	0.129870	Yes	No
XII	3	0.012987	0.038961	Yes	Yes
XIII	4	0.017316	0.069264	Yes	Yes

The failure to take good quality chest radiograph and the failure to set an average appropriate dose of a chest radiograph were found to result in the same hazard score. According to FMEA, the failure to take chest radiograph in correct locus of patient by the radiologist was the least hazardous cause of delay.

4.Discussion

While many studies report that there was no definitive screening test for the early diagnosis of lung cancer (Melamed et al., 1981; Strauss et al., 1993), other studies claim that the patients were diagnosed at an advanced stage since the duration from the initial symptoms of lung cancer until its diagnosis and treatment was long (Jensen et al., 2002). Although rarely discussed, it is well known that diagnosis is delayed by the lack of knowledge and oversights related to patients, doctors, technicians, technology and hospitals.

This study expresses that patient-related causes are the dominant reasons for the diagnosis of lung cancer during the advanced stages, namely Stage IIIB and Stage IV.

The authors record the most crucial problems as the absence of patient's check-up habit and patient's anxiety and worry causing his late admission to doctor.

On the other hand, in several studies, it was reported that the long waiting time for examination in hospital was the reason for late diagnosis (O'Rourke and Edwards. 2000; Mohammed et al., 2011; Gonzalez et al., 2003). Myrdal et al. (2004) concluded that long waiting time had not been related to poor prognosis.

Since this study was undertaken in a private hospital, accessibility to health care and aggressiveness of the diagnostic approach were not determined among the causes of delay in the unit. On the contrary, the authors made use of advanced diagnostic approaches and patients' access to doctor was easy.

We believe that being one of the main factors in late diagnosis, absence of patient's check-up habit has an effect on prognosis. In the early stage, it is possible to diagnose a lung cancer patient with a tumour size of 2.0 cm by means of a chest radiograph. The studies showed that 70-80% of males diagnosed with a Stage I lung cancer could be treated by surgery and added that lung cancer related deaths could be prevented whereas if the cancer were diagnosed at symptomatic stage, mortality rate would be 90% (Melamed and Flehinger, 1984).

Doctors and public health personnel are responsible for giving patients the habit of check-up. In a research conducted in the UK, patient's lack of knowledge and awareness related to symptoms of lung cancer were found to be crucial factors in late diagnosis (Tod et al., 2008). Thus, education of risky groups is of crucial importance.

The American Cancer Society (2002) has thoroughly reviewed the subject of lung cancer screening and issued guidelines that are aimed at doctors and other health care providers. Patients should be asked about their smoking history. Patients who meet the following criteria may be candidates for lung cancer screening: 55 to 74 years old, have at least a 30 pack/year smoking history, are either still smoking or have quit smoking within the last fifteen years.

In their study, Tod and Craven (2006) stated the following for the diagnostic delay in patients with lung cancer:

-The patients think that the cough is due to another health problem, e.g. winter virus, a chronic chest problem, etc.

-The patients think that the problem will clear up if left alone.

-The patients are frightened that the cough may mean something more serious, e.g. lung cancer.

-People who were ex-smokers or non-smokers thought that they had no risk of lung cancer.

-Family practitioners do not follow the guidelines.

In several studies, anxiety was shown to have an impact on patient delay (Arndt et al., 2002; The Ronnie Lippen/Tower Cancer Research Foundation and the Dohring Company, 2008; Mitchell et al., 2008). They concluded that anxiety associated with recognizing a potential cancer symptom had resulted in delayed presentation. Their result is consistent with the findings of this study.

In this study, it was determined that patients had not consulted a doctor due to their anxiety and worry of being diagnosed with lung cancer. It was also found that they had decided to consult a doctor when the symptoms worsened and added that none of the patients had taken chest radiographs in the last six months.

The Six Sigma Methodology is a powerful performance improvement technique that is changing the face of modern healthcare industry today (Taner et al., 2007). Being a method that eliminates faults and errors, Six Sigma makes use of structured statistics as a part of its DMAIC (Define-Measure-Analyse-Improve-Control) tool. This tool finds the main causes behind problems and to reach near perfect processes. It is useful to analyse and modify complicated time-sensitive healthcare processes involving multiple specialists (Taner et al., 2009). It identifies, reduces the causes of delay and thus minimizes the variability in the process (Taner et al, 2013).

To date, Six Sigma Methodology was successfully employed in several areas of health care such as radiology, emergency room, surgical infection sites, intensive care, doctor's turnover intentions, diagnostic imaging, ophthalmology, cardiology, pharmacy and haemodialysis (Cherry and Seshadri, 2000; Miller et al., 2003; Frankel et al., 2005; Eldridge et al., 2006; Taner and Sezen, 2009; Taner et al., 2012; Taner, 2013; Taner et al., 2013; Arafeh et al., 2014; Ekinci et al.).

The authors developed preventive measures for each type of cause in order to bring the overall process under control (Table 6). By brainstorming on the mechanisms underlying the causes, they implemented the following corrective action plan to reduce the causes.

Table 6. Preventative Measure(s) per Root Cause of Delay

Type	Root Cause of Delay	Preventative Measure(s)
I	Absence of patient's check-up habit.	Alert the public on the benefits of having regular check-up by using written and visual media.
II	Late admission of patient to doctor due to anxiety and worry.	Organize regular seminars for public,
		Increase public's socio-psychological level by using written and visual media.
III	Patient's self-prescription.	Restrict patient's access to antibiotics and painkillers,
		Educate patients.
IV	Patient's decision to use alternative medicine after knowing the tumour and not accepting surgery.	Give efficient education to public.
V	Delay in diagnosis due to doctor's direct prescription of medication and patient's avoidance of regular check-up.	Organize seminars for doctors.
VI	Doctor's irregular follow-up of patient's lung nodules that he detected in patient's X-ray films.	Take measures to reduce the workload in hospitals
VII	Incorrect examination of pathological specimen.	Organize Continuing Medical Education (CME)s for pathology doctors ,
		Implement advanced diagnostic methods.
VIII	Misinterpretation of radiologic imaging signs.	Organize efficient CMEs for doctors.
IX	Failure to take good quality chest radiograph.	Continuously re-train technicians.
X	Insufficient imaging due to non-periodic maintenance of tomography equipment.	Recruit biomedical experts to work in hospitals,
		Provide periodic maintenance for biomedical equipment.
XI	Reaching incomplete or incorrect diagnosis due to taking non-contrast tomography.	Increase cooperation between doctors and technicians.
XII	Failure to take chest radiograph in correct locus of patient.	Continuously re-train technicians.
XIII	Failure to set an average effective dose of a chest radiograph.	Continuously re-train technicians.

Conclusion

In this study, the authors applied Six Sigma tools to reduce the late diagnosis of lung cancer. They found that absence of patient's check-up habit, anxiety and worry causing his late admission to doctor were the crucial causes of delay that had led to inoperability.

To reduce the delays that lead to inoperability, the authors advise the following measures to be taken:

-Regular seminars must be held in order to increase the socio-psychological level of the public.

-Written, visual and social media must cooperate with doctors to effectively increase the public's awareness for rare and common symptoms of lung cancer. The public should be made aware that early stage lung cancer could be cured.

-Periodic seminars should be held for the public in hospitals. The public should be made aware that self-prescription might delay the diagnosis.

-With the help of the written, visual and social media; the public must be alerted and encouraged so that they can use regular check-up programs. These programs should be integrated into government policy.

The authors also found that education of the public and patients; CME of doctors; training of technicians; and regular maintenance of biomedical equipment could minimize the delays. More rigorous CME process should be carried out on the doctors. Periodic maintenance of biomedical equipment in hospitals should be made. Training of medical technicians on the functions of the equipment should be repeated.

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